UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): March 10, 2025

MINERALYS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-41614**	**84-1966887**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

150 N. Radnor Chester Road, Suite F200
Radnor, Pennsylvania 19087
(Address of principal executive offices) (Zip Code)

(888) 378-6240
(Registrant's telephone number, include area code)

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	MLYS	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure.

On March 10, 2025, Mineralys Therapeutics, Inc. (the Company) issued a press release announcing positive topline data from its pivotal Launch-HTN Phase 3 and pivotal Advance-HTN Phase 2 trials evaluating the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN). A copy of the press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933 or the Securities Exchange Act of 1934, except as shall be expressly set forth by specific reference in that filing.

Item 8.01. Other Events.

On March 10, 2025, the Company announced positive topline data from its pivotal Launch-HTN Phase 3 and pivotal Advance-HTN Phase 2 trials evaluating the efficacy and safety of lorundrostat for the treatment of uHTN or rHTN. Both trials successfully achieved statistical significance and were clinically meaningful in their pre-specified primary efficacy endpoints and demonstrated a favorable safety and tolerability profile.

Efficacy Results

The Launch-HTN trial was a global, randomized, double-blinded, placebo-controlled Phase 3 trial, which enrolled eligible adult participants who failed to achieve their blood pressure goal despite being on two to five antihypertensive medications. Launch-HTN reflects the real-world setting for clinicians by utilizing automated office blood pressure (AOBP) measurement and allowing participants to stay on their existing medications. The trial met its endpoints demonstrating clinically meaningful, statistically significant mean reduction from baseline in placebo-adjusted systolic blood pressure at week six and the benefit was sustained with potential further reduction through week 12.

Launch-HTN Phase 3 Trial (automated office systolic blood pressure measure, n=1,083)				
	Week 6 (50 mg pooled)		**Week 12**	
	Absolute Reduction	Placebo-Adjusted Reduction	Absolute Reduction	Placebo-Adjusted Reduction
50 mg	-16.9 mmHg	-9.1 mmHg (p<0.0001)*	-19.0 mmHg	-11.7 mmHg (p<0.0001)
50 to100 mg			-15.7 mmHg	-8.4 mmHg (p=0.0016)
* *Primary endpoint*				

- The change in blood pressure in response to lorundrostat in subjects using two background antihypertensives (uncontrolled) or three to five (resistant) were similar, and both were statistically significantly different from the response in those taking placebo.

Key characteristics of subjects enrolled in the Launch-HTN trial include: approximately 63% had a body mass index (BMI) greater than or equal to 30kg/m2, approximately 47% were women, and approximately 29% were Black or African American.

The Advance-HTN trial was a randomized, double-blind, placebo-controlled Phase 2 pivotal trial that evaluated the efficacy and safety of lorundrostat for the treatment of confirmed uHTN or rHTN, when used as add-on therapy to an optimized background treatment of two or three antihypertensive medications in adult subjects. The trial met its primary endpoint, with placebo-adjusted reduction from baseline in systolic blood pressure assessed with 24-hour average blood pressure measurement at week 12 of -7.9 mmHg in subjects treated with 50 mg of lorundrostat. Other prespecified outcome measures, including measures of efficacy in the dose-escalation cohort,

safety and tolerability, were consistent with those observed in the Launch-HTN trial. Key characteristics of subjects enrolled in the Advance-HTN trial include: approximately 66% had a BMI greater than or equal to 30kg/m2, approximately 40% were women, and approximately 50% were Black or African American.

Additional details regarding the results from Advance-HTN are embargoed until presentation on March 29, 2025, at the American College of Cardiology Scientific Sessions.

Safety and Tolerability Results

The Company believes clinical safety findings, including hypotension, serum potassium, eGFR and serum cortisol, from both pivotal trials, support a favorable benefit-risk profile.

- In the Launch-HTN trial there were 12 subjects (2.2%) and two subjects (0.7%) with treatment-emergent serious adverse events (SAEs) in the 50 mg and 50 mg with optional dose escalation to 100 mg arms, respectively, compared with eight subjects (3.0%) in the placebo arm. There was only one subject (0.1%) in the trial with treatment-related SAEs that occurred in the 50 mg arm.
- The incidence of hyperkalemia (serum potassium above 6.0 mmol/L) in the 50 mg and 50 mg to 100 mg arms, respectively, was 1.1% and 1.5% in the Launch-HTN trial and 5.3% and 7.4% in the Advance-HTN trial.

A summary of safety data from the Launch-HTN trial is included below.

	Placebo N=270			**Lorundrostat 50 mg QD N=538**			**Lorundrostat 50 mg to 100 mg QD N=270**			**Total N=1,078**		
	%	**N**	**Events**	**%**	**N**	**Events**	**%**	**N**	**Events**	**%**	**N**	**Events**
SAEs	**3.3**	**9**	**13**	**2.4**	**13**	**15**	**0.7**	**2**	**3**	**2.2**	**24**	**31**
TEAEs	36.3	98	202	53.7	289	636	55.9	151	313	49.9	538	1,151
Drug-Related	18.9	51	83	38.8	209	389	39.3	106	191	34.0	366	663
AESI	11.1	30	37	23.0	124	164	24.1	65	91	20.3	219	292
Leading to dosing discontinuation	1.9	5	6	2.6	14	17	1.5	4	6	2.1	23	29
Leading to death	0.0	0	0	0.0	0	0	0.0	0	0	0.0	0	0

SAEs: Serious Adverse Events; TEAEs: Treatment Emergent Adverse Events; AESI: Adverse Events of Special Interest

The Company believes the Advance-HTN and Launch-HTN results demonstrate the opportunity of lorundrostat in third line or later treatment.

The ongoing Transform-HTN open-label extension trial allows subjects to continue to receive lorundrostat and generate additional safety and efficacy data.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Press Release Issued March 10, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Forward Looking Statements

The Company cautions you that statements contained in this report regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on the Company's current beliefs and expectations and include, but are not limited to, statements regarding: the potential therapeutic benefits of lorundrostat; the Company's expectation that Advance-HTN and Launch-HTN may serve as pivotal trials in any submission of a new drug application (NDA) to the United States Food and Drug Administration (FDA); the Company's ability to evaluate lorundrostat as a potential treatment for CKD, uHTN or rHTN; and the planned future clinical development of lorundrostat and the timing thereof. Actual results may differ from those set forth in this report due to the risks and uncertainties inherent in the Company's business, including, without limitation: topline results that the Company reports are based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; the Company's future performance is dependent entirely on the success of lorundrostat; potential delays in the commencement, enrollment and completion of clinical trials and nonclinical studies; later developments with the FDA may be inconsistent with the feedback from the completed end of Phase 2 meeting, including whether the proposed pivotal program will support registration of lorundrostat which is a review issue with the FDA upon submission of an NDA; the results of the Company's clinical trials, including the Advance-HTN and Launch-HTN trials, may not be deemed sufficient by the FDA to serve as the basis for an NDA submission or regulatory approval of lorundrostat; the Company's dependence on third parties in connection with manufacturing, research and clinical and nonclinical testing; unexpected adverse side effects or inadequate efficacy of lorundrostat that may limit its development, regulatory approval and/or commercialization; unfavorable results from clinical trials and nonclinical studies; results of prior clinical trials and studies of lorundrostat are not necessarily predictive of future results; regulatory developments in the United States and foreign countries; the Company's reliance on its exclusive license with Mitsubishi Tanabe Pharma to provide it with intellectual property rights to develop and commercialize lorundrostat; and other risks described in the Company's filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in the Company's annual report on Form 10-K, and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MINERALYS THERAPEUTICS, INC.

Date: March 10, 2025

By: /s/ Adam Levy
Name: Adam Levy
Title: Chief Financial Officer and Secretary

Mineralys Therapeutics Announces Positive Topline Results from Launch-HTN and Advance-HTN Pivotal Trials of Lorundrostat for the Treatment of Uncontrolled or Resistant Hypertension

– Launch-HTN met its primary endpoint with lorundrostat 50 mg dose achieving a 16.9 mmHg reduction in systolic blood pressure, and a 9.1 mmHg placebo-adjusted reduction (p-value < 0.0001) assessed by automated office blood pressure at week 6 –

– Launch-HTN met a predefined endpoint with lorundrostat 50 mg dose achieving a 19.0 mmHg reduction in systolic blood pressure, and an 11.7 mmHg placebo-adjusted reduction (p-value < 0.0001) assessed by automated office blood pressure at end of treatment, week 12 –

– Advance-HTN met its primary endpoint with lorundrostat 50 mg dose achieving a highly statistically significant 7.9 mmHg placebo-adjusted reduction assessed by 24hr ABPM at end of treatment, week 12 –

– Lorundrostat demonstrated a favorable safety and tolerability profile in both pivotal trials –

– Full results from Advance-HTN to be presented on March 29, 2025, at the American College of Cardiology Scientific Sessions –

– Conference call today at 8:00 a.m. ET –

RADNOR, PA – March 10, 2025 – Mineralys Therapeutics, Inc. (Nasdaq: MLYS), a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, chronic kidney disease (CKD), obstructive sleep apnea (OSA) and other diseases driven by dysregulated aldosterone, today announced positive topline data from its pivotal Launch-HTN Phase 3 and pivotal Advance-HTN Phase 2 trials evaluating the efficacy and safety of lorundrostat for the treatment of uncontrolled hypertension (uHTN) or resistant hypertension (rHTN). Both trials successfully achieved statistical significance and were clinically meaningful in their pre-specified primary efficacy endpoints and demonstrated a favorable safety and tolerability profile.

“The positive results and clinically meaningful reduction in blood pressure observed in the Launch-HTN and Advance-HTN trials show us that lorundrostat has the potential to be a transformative new therapy for the approximately 15 to 20 million patients with uncontrolled hypertension in the United States,” stated Jon Congleton, Chief Executive Officer of Mineralys Therapeutics. “We have now completed three successful clinical trials demonstrating the efficacy, safety and tolerability of lorundrostat and the importance of targeting dysregulated aldosterone. We believe the clinical profile observed for lorundrostat supports the potential regulatory approval of this novel agent and its significant commercial value. We appreciate the commitment and hard work of the clinical investigators, site staff, the Mineralys and Cleveland Clinic research teams, and especially the trial subjects who volunteered to participate in our program.”

Efficacy Results

The Launch-HTN trial was a global, randomized, double-blinded, placebo-controlled Phase 3 trial, which enrolled eligible adult participants who failed to achieve their blood pressure goal despite being on two to five antihypertensive medications. Launch-HTN reflects the real-world setting for clinicians by utilizing

automated office blood pressure (AOBP) measurement and allowing participants to stay on their existing medications. The trial met its endpoints demonstrating clinically meaningful, statistically significant mean reduction from baseline in placebo-adjusted systolic blood pressure at week six and the benefit was sustained with potential further reduction through week 12.

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- The change in blood pressure in response to lorundrostat in subjects using two background antihypertensives (uncontrolled) or three to five (resistant) were similar, and both were statistically significantly different from the response in those taking placebo.

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- The incidence of hyperkalemia (serum potassium above 6.0 mmol/L) in the 50 mg and 50mg to 100mg arms, respectively, was 1.1% and 1.5% in the Launch-HTN trial and 5.3% and 7.4% in the Advance-HTN trial.

“The Launch-HTN study evaluating novel drug lorundrostat is one of the largest blood pressure studies in recent times and demonstrates its benefit in lowering blood pressure and its safety in a diverse group of patients whose hypertension is not well controlled,” stated Manish Saxena MBBS, Hypertension

Specialist from Barts Health NHS Trust. “Uncontrolled and resistant hypertension remains a global health concern as it continues to be the leading cause of cardiovascular deaths, heart attacks and strokes. Given today’s announcement, lorundrostat could be a good treatment option for millions of patients with high blood pressure."

Mineralys plans to provide additional data from these two pivotal trials at upcoming medical conferences and in peer-reviewed publications.

The ongoing Transform-HTN open-label extension trial allows subjects to continue to receive lorundrostat and generate additional safety and efficacy data.

Conference Call

The Company’s management team will host a conference call today, March 10, 2025, at 8:00 a.m. ET. To access the call, please dial 1-877-704-4453 in the U.S. or 1-201-389-0920 outside the U.S. A live webcast of the conference call may be found here. A replay of the call will be available on the “News & Events” page in the Investor Relations section of the Mineralys Therapeutics website (click here).

About Hypertension

Having sustained, elevated blood pressure (or hypertension) increases the risk of heart disease, heart attack and stroke, which are leading causes of death in the U.S. In 2020, more than 670,000 deaths in the U.S. included hypertension as a primary or contributing cause. Hypertension and related health issues resulted in an estimated annual economic burden of about $219 billion in the U.S. in 2019.

Less than 50 percent of hypertension patients achieve their blood pressure goal with currently available medications. Dysregulated aldosterone levels are a key factor in driving hypertension in approximately 30 percent of all hypertensive patients.

About Lorundrostat

Lorundrostat is a proprietary, orally administered, highly selective aldosterone synthase inhibitor being developed for the treatment of uHTN and rHTN as well as CKD and OSA. Lorundrostat was designed to reduce aldosterone levels by inhibiting CYP11B2, the enzyme responsible for its production. Lorundrostat has 374-fold selectivity for aldosterone-synthase inhibition versus cortisol-synthase inhibition in vitro, an observed half-life of 10-12 hours and demonstrated approximately a 70% reduction in plasma aldosterone concentration in hypertensive subjects.

In a Phase 2, proof-of-concept trial (Target-HTN) in uncontrolled or resistant hypertensive subjects, once-daily lorundrostat demonstrated statistically significant and clinically meaningful blood pressure reduction in both automated office blood pressure measurement and 24-hour ambulatory blood pressure monitoring. Adverse events observed were a modest increase in serum potassium, decrease in estimated glomerular filtration rate, urinary tract infection and hypertension with one serious adverse event possibly related to study drug being hyponatremia.

About Launch-HTN

The Launch-HTN trial (NCT06153693) was a global, randomized, double-blinded, placebo-controlled Phase 3 trial, which enrolled eligible adult participants who failed to achieve their blood pressure goal despite being on two to five background antihypertensive medications. Eligible subjects were randomized to one of three arms: placebo, lorundrostat 50 mg once daily (QD), and lorundrostat 50 mg QD and then

titrated to 100 mg QD, as needed, at week six. The primary endpoint of the trial was the change from baseline in systolic blood pressure versus placebo after six weeks of treatment, as measured by automated office blood pressure monitoring.

About Advance-HTN

The Advance-HTN trial (NCT05769608) was a randomized, double-blind, placebo-controlled Phase 2 clinical trial that evaluated the efficacy and safety of lorundrostat for the treatment of uHTN or rHTN, when used as an add-on therapy to a standardized background treatment of two or three antihypertensive medications in adult subjects. Subjects who meet screening criteria had their existing hypertension medications discontinued and start on a standard regimen of an angiotensin II receptor blocker (ARB) and a diuretic, if previously on two medications, or a standard regimen of ARB, diuretic and calcium channel blocker if previously on three to five medications. Subjects who remained hypertensive despite the standardized regimen were then randomized into three cohorts and treated for twelve weeks: lorundrostat 50 mg QD, lorundrostat 50 mg QD, and an option to titrate to 100 mg QD at week four based on defined criteria or placebo. The trial's primary endpoint was the change in 24-hour ambulatory systolic blood pressure at week twelve from baseline for active cohorts versus placebo.

About Mineralys

Mineralys Therapeutics is a clinical-stage biopharmaceutical company focused on developing medicines to target hypertension, CKD, OSA and other diseases driven by dysregulated aldosterone. Its initial product candidate, lorundrostat, is a proprietary, orally administered, highly selective aldosterone synthase inhibitor that Mineralys Therapeutics is developing for the treatment of cardiorenal conditions affected by dysregulated aldosterone, including hypertension, CKD and OSA. Mineralys is based in Radnor, Pennsylvania, and was founded by Catalys Pacific. For more information, please visit https://mineralystx.com. Follow Mineralys on LinkedIn and Twitter.

Forward Looking Statements

Mineralys Therapeutics cautions you that statements contained in this press release regarding matters that are not historical facts are forward-looking statements. The forward-looking statements are based on our current beliefs and expectations and include, but are not limited to, statements regarding: the potential therapeutic benefits of lorundrostat; the Company's expectation that Advance-HTN and Launch-HTN may serve as pivotal trials in any submission of a new drug application (NDA) to the United States Food and Drug Administration (FDA); the Company's ability to evaluate lorundrostat as a potential treatment for CKD, uHTN or rHTN; and the planned future clinical development of lorundrostat and the timing thereof. Actual results may differ from those set forth in this press release due to the risks and uncertainties inherent in our business, including, without limitation: topline results that we report are based on a preliminary analysis of key efficacy and safety data, and such data may change following a more comprehensive review of the data related to the clinical trial and such topline data may not accurately reflect the complete results of a clinical trial; our future performance is dependent entirely on the success of lorundrostat; potential delays in the commencement, enrollment and completion of clinical trials and nonclinical studies; later developments with the FDA may be inconsistent with the feedback from the completed end of Phase 2 meeting, including whether the proposed pivotal program will support registration of lorundrostat which is a review issue with the FDA upon submission of an NDA; the results of our clinical trials, including the Advance-HTN and Launch-HTN trials, may not be deemed sufficient by the FDA to serve as the basis for an NDA submission or regulatory approval of lorundrostat; our dependence on third parties in connection with manufacturing, research and clinical and nonclinical testing; unexpected adverse side effects or inadequate efficacy of lorundrostat that may limit its

development, regulatory approval and/or commercialization; unfavorable results from clinical trials and nonclinical studies; results of prior clinical trials and studies of lorundrostat are not necessarily predictive of future results; regulatory developments in the United States and foreign countries; our reliance on our exclusive license with Mitsubishi Tanabe Pharma to provide us with intellectual property rights to develop and commercialize lorundrostat; and other risks described in our filings with the Securities and Exchange Commission (SEC), including under the heading "Risk Factors" in our annual report on Form 10-K, and any subsequent filings with the SEC. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof, and we undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, which is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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